

RECEIVED  
CENTRAL FAX CENTER  
JUL 27 2007

### REMARKS

Reconsideration of this application, as amended, is respectfully requested.

Consideration and entry of this amendment is respectfully requested as it brings the application into condition for an allowance or in better form for consideration on appeal. The amendment does not raise any substantial new issues that would require any burdensome search by the Examiner.

#### A. Interview Summary

Applicants' representatives, (Emily Miao and Elaine Chang), thank the Examiner and SPE Michael Szperka for the interview conducted on July 20, 2007. During the interview, Applicants' representatives and the Examiners discussed the pending rejections under 35 U.S.C. §§ 112, 102, and 103, and potential amendments that would overcome the rejections. No agreement was reached, but Applicants have attempted to address the Examiners' concerns in the amendments to the claims and the remarks presented here.

#### B. Claim Amendments

Claims 44-48, 73, 75-80 are pending in this application. Claims 49-52 are canceled, and claims 44, 45, 48, and 73 are amended. Support for the claim amendments can be found throughout the specification as originally filed, for example, on p.1, lines 1-2 and lines 4-7; p.5, last paragraph to p.6, first paragraph; p. 21 last paragraph to p. 22 second paragraph; and Tables on pp. 25, 27, and last line on p. 30. New claims 75-80 are added, which are fully supported by the specification as originally filed. Exemplary support for the new claims can be found on p.13, third paragraph; p.18, first paragraph; p.22, first and second paragraphs; and p. 26, example 3. Thus, the amendments do not constitute new matter.

#### C. Rejections under 35 U.S.C. §112, First Paragraph Written Description

The Examiner rejected Claims 44-52, and 73-74 for alleged failing to comply with the written description requirement under 35 U.S.C. § 112, first paragraph. In view of the claim amendments and remarks made in the Response filed on June 15, 2007, and the claim

amendments made herein, Applicants respectfully submit that the rejections are now moot. Reconsideration and withdrawal of the rejections are thus earnestly solicited.

**D. Rejections under 35 U.S.C. §112, Second Paragraph**

The Examiner rejected Claims 44-52, and 73-74 for allegedly being indefinite under 35 U.S.C. § 112, second paragraph. In view of the claim amendments and remarks made in the Response filed on June 15, 2007, and the claim amendments made herein, Applicants respectfully submit that the rejections are now moot. Reconsideration and withdrawal of the rejections are thus earnestly solicited.

**E. Rejections under 35 U.S.C. § 102**

The Examiner rejected Claim 44, 47-49, 51-52, and 73 under 35 U.S.C. § 102(b) as being unpatentable over Fleming, U.S. Patent No. 5,149,626 (hereinafter "Fleming"), and Herzberg et al. (EP 0 171 150 A2, hereinafter "Herzberg"). Claims 49, and 51-52 are now canceled. The Cancellation has rendered the rejection moot.

As a threshold matter, the Federal Circuit has stated that for prior art to anticipate under section 102, every element of the claimed invention must be identically disclosed in a single reference. *Corning Glass Works v. Sumitomo Electric*, 9 U.S.P.Q.2d 1962, 1965 (Fed. Cir. 1989). The exclusion of a claimed element, no matter how insubstantial or obvious, from a reference is enough to negate anticipation. *Connell v. Sears, Roebuck & Co.*, 220 U.S.P.Q 193, 198 (Fed. Cir. 1983).

Applicants respectfully traverse the rejection, but have nevertheless amended the claims. Applicants submit that amended claim 44 is directed to a method for detection of a plurality of analytes in a sample, the plurality of analytes derived from one pathogen, wherein the method comprises the steps of separately measuring presence or amount of a signal generated by the signal generating group bound to the first and second test areas and calculating a test area-specific cut-off index (COI) on each test area wherein a COI larger than 1 for one test area is indicative for presence of a specific analyte in the sample. Neither Fleming nor Herzberg teaches or suggests, *inter alia*, a method for detection of a plurality of analytes in a sample, the plurality

of analytes derived from one pathogen, wherein the method comprises the steps of separately measuring presence or amount of a signal generated by the signal generating group bound to the first and second test areas, and calculating a test area-specific cut-off index (COI) on each test area wherein a COI larger than 1 for one test area is indicative for presence of a specific analyte in the sample. Thus, neither cited art teaches every element of the claimed invention. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 102(b) over Fleming and Herzberg.

**F. Rejection under 35 U.S.C. §103(a)**

The Examiner rejected Claims 49-52 under 35 U.S.C. § 103(a) as being unpatentable over Ekins et al., U.S. Patent No. 5,516,635 (hereinafter "Ekins"), in view of Schonbrunner, UK Patent Application Publication GB 2 313 666 A (hereinafter "Schonbrunner"). The Examiner also rejected Claims 44-46, 48 and 73 under 35 U.S.C. § 103(a) as being unpatentable over Ekins, in view of Schonbrunner, and in further view of Lancaster, U.S. Patent No. 3,568,735 (hereinafter "Lancaster"). The Examiner further rejected Claims 47 and 74 under 35 U.S.C. § 103(a) as being unpatentable over Ekins, in view of Schonbrunner and Lancaster, and further in view of O'Connor et al. U.S. Patent No. 5,627,026 (hereinafter "O'Connor").

A claimed invention is unpatentable if the differences between it and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a); *see Graham v. John Deere Co.*, 383 U.S. 1, 14 (1966). The ultimate determination of whether an invention is or is not obvious is based on underlying factual inquiries including: (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; (3) resolving the level of ordinary skill in the pertinent art; and (4) evaluating evidence of secondary considerations. *See Graham*, 383 U.S. at 17-18.

The MPEP clearly provides the criteria for establishing a *prima facie* case of obviousness: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings, (2) there must be a reasonable expectation of success, and (3) the prior art reference (or references when combined) must teach or suggest all the claim limitations.

MPEP § 2142. The obviousness inquiry set forth in *Graham* focuses on whether the prior art as a whole teaches, suggests, or motivates one of ordinary skill in the art to make the invention and whether the skilled artisan would have a reasonable expectation of making and using it. *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991). The suggestion, teaching, or motivation to combine may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved. *See Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996).

Applicants respectfully traverse the rejections, but have nevertheless amended the claims. Claims 49-52, and 74 have been canceled. The cancellation has rendered the rejections moot. Applicants submit that amended claim 44 is directed to a method for detection of a plurality of analytes in a sample, the plurality of analytes derived from one pathogen, wherein the method comprises the steps of separately measuring presence or amount of a signal generated by the signal generating group bound to the first and second test areas and calculating a test area-specific cut-off index (COI) on each test area wherein a COI larger than 1 for one test area is indicative for presence of a specific analyte in the sample. None of the cited references, alone or in combination, teaches or suggests a method for detection of a plurality of analytes, comprising a step of calculating a test area-specific cut-off index on each test area wherein a COI larger than 1 for one test area is indicative for presence of a specific analyte in the sample. The cited references, when considered as a whole, would not have rendered the claimed invention obvious. Further, even the combination of the references does not teach every element of the claims. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a).

#### **G. Double Patenting**

Claims 44-52 and 73-74 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-34 of U.S. Patent No. 6,815,217 ("the '217 patent"). The cancellation of claims 49-52 and 74 has rendered the rejection moot.

The subjects of the '217 patent and the present application are patentably distinct. Claims 1-34 of the '217 patent are directed to a device, a method, and a kit for detecting an analyte in a sample containing at least one interfering substance. Specifically, claims 1-18 of the '217 patent are directed to an assay device for use in determination of an analyte in a sample that comprises

at least one interfering substance, said device comprising a solid phase support; a test area comprising test area components wherein the at least one interfering substance non-specifically binds to one or more test area components; and a control area comprising control area components in a separate defined region of the support, wherein the control area components are the same as at least some of the test area components, and wherein the at least one interfering substance non-specifically binds to one or more control area components.

Claims 19-33 of the '217 patent are directed to an assay method for determining an analyte in a sample that comprises at least one interfering substance, said method comprising applying the sample to the solid support that comprises a test area and a control area, applying a marker to the solid phase support to generate a detectable signal; and measuring the signal generated by the marker in the test area and in the control area.

Claim 34 of the '217 patent is directed to a kit for use in the determination of an analyte in a sample that comprises at least one interfering substance, said kit comprising a solid phase support including a test area and a control area; and a marker capable of binding to the analyte and to the at least one interfering substance.

The present claims 44-48, 73, 75-80, on the contrary, concerns a method for detection of a plurality of analytes in a sample, the plurality of analytes derived from one pathogen, and the method comprising the steps of: providing a solid phase comprising a non-porous support, at least two spatially separate test areas, wherein a first test area has a first analyte-specific receptor bound thereto, and a second test area has a second analyte-specific receptor bound thereto, each spatially separate test area having no more than one type of analyte-specific receptor bound thereto, and wherein the first receptor and the second receptor bind to different analytes in the sample; contacting the sample with the solid phase and with a detection reagent comprising one or more third receptors to allow binding of the third receptors to the analytes bound to the test area, each third receptor directly or indirectly labeled with a signal generating group; separately measuring presence or amount of a signal generated by the signal generating group bound to the first and second test areas; and calculating a test area-specific cut-off index (COI) on each test area wherein a COI larger than 1 for one test area is indicative for presence of a specific analyte in the sample.

Applicants submit that claims 1-34 of the '217 patent and claims 44-48, 73 and 75-80 of the instant application are patentably distinct. The subject matter of claims 1-34 of the '217

RECEIVED  
CENTRAL FAX CENTER  
JUL 27 2007

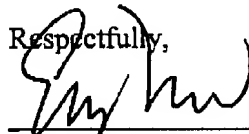
patent concerns the use of control spots; whereas the subject matter of claims 44-48, 73, 75-80 of the current invention concerns detection of a plurality of analytes in a sample based on test area-specific cut-off indices. In view of the differences between the present application and claim 1-34 of the '217 patent, Applicants respectfully request that the double patenting rejection be withdrawn.

H. Conclusion

Reconsideration of this application is respectfully requested and a favorable determination is earnestly solicited. The Examiner is invited to contact the Applicants' undersigned representative at (312) 913-2126 if the Examiner believes that this would be helpful in expediting prosecution of this application.

Date: July 27, 2007

Respectfully,



Emily Miao

Registration No. 35,285

McDonnell Boennen Hulbert & Berghoff LLP  
300 South Wacker Drive, Suite 3100  
Chicago, IL 60606  
Telephone: 312 913 0001  
Facsimile: 312 913 0002